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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,838	02/21/2002	Tania C. Sorrell	1274/62620/PJP	4331

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,838

Applicant(s)

SORRELL ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15-27, 34-45 and 51-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15-27, 34-45 and 51-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0306 01-05-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 9 January 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 10-14, 28-33, and 46-50 have been cancelled. Claims 1-9, 15-27, 34-45 and 51-54 are currently pending.

Information Disclosure Statement

The Information Disclosure Statement filed 5 January 2005 has been considered. A signed copy of PTO Form-1449 is included with this Office Action.

Priority

Priority to US Provisional Application 60/270,367 filed 21 February 2001 is hereby acknowledged.

Drawings

The drawings submitted 21 February 2002 are accepted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 15-27, 34-45, and 51-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Somorjai et al. (Magnetic Resonance in Medicine (1995) Vol. 33, pages 257-263; PTO Form 1449 reference 21), in view of Delpassand et al. (Journal of Clinical Microbiology (1995) May, page 1258-1262, PTO Form 1449 Reference 5), for the reason's set forth in the previous Office Actions (see Non-final of 9/30/04 and Final of 7/6/05).

Response to Applicant's Arguments Regarding 35 USC 103(a)

1. *Applicant argues that the claims have been further amended to "more clearly recite that the claimed method enables classifying microorganisms of unknown species within the same genus into known species within the same genus. The present claimed invention enables one to discriminate between closely related species, i.e., species within the same genus, by using a linear discriminate classifier".*

This is not persuasive. The instant rejection is not one of enablement, rather a rejection based upon the combination or the references above. Somorjai et al. in view of Delpassand teach all of the limitations of the instant claims, as has been recited previously. In reference to Delpassand, he teaches the classification of species within the same genus. He specifically teaches the discrimination between *S. sonnei* and *S. flexneri*, using NMR, for example, at page 1260, column 2, last paragraph.

2. *Applicant further argues that the Delpassand reference "discusses obtaining MR spectra from a few widely different genera of bacteria, namely E. coli, K. pneumoniae, P. aeruginosa, S. aureus, and E. faecalis. The five bacteria listed are different genera, and no two of*

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them are in the same genera. Moreover, in each case, the genera was identified [by determined] by picking the two most prominent peaks in the spectra of each (by visual inspection only) to distinguish between the genera, and not within genera. They acknowledged that more isolates would have to be studied to verify the method, and they did not use a statistical classification strategy for the analysis”.

This is not persuasive. The Delpassand reference clearly teaches that two species of *Shigella*, *S. sonnei* and *S. flexneri*, could be distinguished from one another. (page 1260, column 2, last paragraph). Further, Delpassand states that “the spectrum of *S. flexneri* had a signal of medium intensity at 3.80ppm which was absent in the spectrum of *S. sonnei*, thereby allowing species differentiation. Similarly, *E. faecium* (one strain) was differentiated from 10 strains of *E. faecalis*, the spectrum of the former bacterium having a signal of medium intensity at 3.67 ppm, which was absent in the 10 spectra of *E. faecalis*” (page 1261, column 1, paragraph 1).

Further, Delpassand et al. do classify signal intensities relative to one another (page 1260, column 2, paragraph 1). It is noted that the Somorjai et al. reference is relied upon to teach the classification scheme, as recited in the instant claims.

3. *Applicant argues that “with regard to the differentiation between species, they compared only one strain (isolate) of Shigella flexneri with one strain of Shigella sonnei. They also claimed in the discussion without showing any data that Enterococcus faecalis could be distinguished from Enterococcus faecium by NMR spectroscopy. Neither of these claims is valid on the basis of testing only one strain (Shigella) and showing no data (Enterococcus). Biological variation occurs between bacterial strains, which is why substantial numbers showing*

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reproducible characteristics are needed to build up a reliable, fully discriminatory, database to enable one to reliably distinguish one species from another in the same genera”.

This is not persuasive. Applicant admits that Delpassand, does in fact, teach the discrimination between different species of bacteria, which is contrary to what Applicant stated above. In addition, Applicants interpretation of the number of strains is not accurate. Delpassand, as quoted above, teaches that one strain of *E. faecium* was differentiated from 10 strains of *E. faecalis* (page 1261, column 1, paragraph 1). Lastly, Applicants assessment of the enablement of the disclosure of Delpassand does not pertain to the instant rejection, which is a prior art rejection. Delpassand teaches the limitations set forth in the instant claims.

4. *Applicant argues that it “would not have been obvious to combine Delpassand’s approach with the SCS method of Somorjai because successful introduction of SCS to the identification of bacteria requires the accumulation of a large data set of closely and distantly related organisms and such methodology would not have occurred to one of ordinary skill in the art. The Delpassand reference used only statistically non-significant number of strains and used only visual inspection, and nowhere suggested the use of a statistical classifier. Further, the SCS method of Somorjai did not disclose the concept of discriminating closely and distantly related species within the same genus”.*

This is not persuasive. As stated in the previous Office Action, while Somorjai et al. do not teach the use of this method for identification and classification of bacterial species, Delpassand et al. et al. do show that NMR is a useful technique to rapidly identify pathogens, including bacteria, by providing a “fingerprint” within the proton spectrum (see entire article). It

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would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the method and classifier of Somorjai et al. to identify and classify bacteria (as was shown by Delpassand et al. to be distinguishable through NMR spectra). One would have been motivated to do so because Somorjai et al. explicitly state that, although the example in the paper is directed to the identification of thyroid neoplasms, it could be used for any biomedical data. They state that “we introduce and apply a new classification strategy called computerized consensus diagnosis. Its purpose is to provide a robust, reliable classification of biomedical data (see abstract)”. Somorjai et al. only use eight unknown samples and eight known samples, hardly a statistically significant number. Further, Delpassand et al. do suggest using a classifier to analyze spectral peaks (page 1260, column 2, paragraph), further supporting that it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the classifier of Somorjai in the method of Delpassand.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

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available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 30, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow

Patent Examiner